



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Prospective Grant of an Exclusive Patent License: Development of a Bispecific T Cell

#### Engager for the Treatment and Cure of HIV-1

**AGENCY:** National Institutes of Health, HHS.

**ACTION:** Notice.

**SUMMARY:** The National Cancer Institute, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive Patent License to practice the inventions embodied in the Patents and Patent Applications listed in the Supplementary Information section of this notice to Gilead Sciences, Inc. (“Gilead”) located in Foster City, CA.

**DATES:** Only written comments and/or applications for a license which are received by the National Cancer Institute’s Technology Transfer Center on or before **[INSERT DATE 15 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]** will be considered.

**ADDRESSES:** Requests for copies of the patent application, inquiries, and comments relating to the contemplated an Exclusive Patent License should be directed to: Rose M. Freel, Ph.D., Senior Licensing and Patenting Manager, NCI Technology Transfer Center, 8490 Progress Drive, Suite 400, Frederick MD 21701 (for business mail), Telephone: (301)624-8775; E-mail: [rose.freel@nih.gov](mailto:rose.freel@nih.gov).

#### **SUPPLEMENTARY INFORMATION:**

##### **Intellectual Property**

United States Provisional Patent Application No. 61/347,088, filed May 21, 2010 and entitled “High-affinity fully functional soluble single-domain human CD4, antibodies, and related fusion proteins” [HHS Reference No. E-103-2010/0-US-01];

PCT Patent Application PCT/US2011/037439, filed May 20, 2011 and entitled “High-affinity fully functional soluble single-domain human CD4, antibodies, and related fusion proteins” [HHS Reference No. E-103-2010/0-PCT-02];

United States Patent No. 8,911,728, granted December 16, 2014, corresponding to US Application No. 13/699,535, filed January 11, 2013, entitled “High-affinity fully functional soluble single-domain human CD4, antibodies, and related fusion proteins” [ HHS Reference No. E-103-2010-1-US-03]; and European Patent Application No. 21185510.1, filed July 14, 2021, entitled “High-affinity fully functional soluble single-domain human CD4, antibodies, and related fusion proteins” [HHS Reference No. E-103-2010-1-EP-04].

The patent rights in these inventions have been assigned and/or exclusively licensed to the government of the United States of America.

The prospective exclusive license territory may be worldwide and the field of use may be limited to the use of the Licensed Patent Rights for the following: “For use in an HIV Bispecific T cell engager construct comprising the CD4 mD1 which will be utilized in therapeutic regimens to treat and cure people living with HIV.”

This technology discloses highly soluble and stable single-domain sCD4 proteins that have therapeutic potential for inhibition of HIV-1 viral entry into cells. CD4 is a glycoprotein present on the surface of mature CD4<sup>+</sup> T cells and is the primary receptor allowing the entry of HIV-1 into cells. The interaction between the CD4 protein on the cell surface and the viral envelope glycoprotein is key for infecting a cell. As a result, the single-domain sCD4 proteins described in this invention have potential uses in a variety of therapeutic strategies attempting to prevent the interaction between cellular CD4 and the viral envelope and therefore, inhibition of viral entry.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR Part 404. The prospective exclusive license will be royalty bearing, and the prospective exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the National Cancer Institute receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR Part 404.

In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a license application, will not be treated confidentially, and may be made publicly available.

License applications submitted in response to this Notice will be presumed to contain business confidential information and any release of information in these license applications will be made only as required and upon a request under the Freedom of Information Act, 5 USC 552.

Dated: September 21, 2021.

**Richard U. Rodriguez,**

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